Instructions for Paper Submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)

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TBD

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I. Introduction

Commercial processors engaged in the manufacturing, processing, or packing of acidified foods (AF) and/or thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as "low-acid canned foods" or "LACF")[1] are subject to the registration requirements of 21 CFR 108.25(c)(1) (for AF) or 21 CFR 108.35(c)(1) (for LACF), as well as the process filing requirements of 21 CFR 108.25(c)(2) (for processors of AF) or 21 CFR 108.35(c)(2) (for processors of LACF). There are two basic types of such required submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following forms:
  - Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)
  - Form FDA 2541e (Food Process Filing for Acidified Method)
  - Form FDA 2541f (Food Process Filing for Water Activity /Formulation Control Method)
    Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems)

This document provides detailed instructions on:

- How to submit process filings by using a *paper* Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method).
- Form FDA 2541d is intended for low-acid food products where the growth of microorganisms is controlled through the application of heat to foods.

This document does not provide:

[1] Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as "cans," the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term (and its abbreviation, LACF) for the purposes of this document.

- Process filing instructions for low-acid food products where the growth of microorganisms is controlled through the amount of water available for microbiological growth (i.e. "water control" products), and for low-acid food products where the growth of microorganisms is controlled through multiple physical and/or physicochemical hurdles (i.e. "formulation control" products). The process filing for such products is instead covered by Form FDA 2541f.
- Instructions for *electronic* submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method);
- Instructions for submitting process filing Forms FDA 2541e, FDA 2541f, and FDA 2541g in either electronic or paper format; or
- Instructions for submitting plant registration Form FDA 2541 in either electronic or paper format.

For additional information about registration and process filing for commercial processors of AF and LACF, see our guidance entitled "Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format" (Ref. 1 and the appendices in Reference 1.)

II. How to Submit Process Filing Form FDA 2541d by Paper

A. General Information

Form FDA 2541d contains 10 sections (Sections A through J).

- All mandatory fields on Form FDA 2541d must be completed. Only two questions are optional:
  - Section A, Question 1 (Food Product Group) requests optional information.
  - Section D, Question 2 (Net Weight (Optional)) requests optional information.
- Information you provide on Form FDA 2541d should be in English.
- When you manufacture, process, or pack a product in more than one container size or type, you are required to submit a separate Form FDA 2541d for each container size and type.
- You may report multiple forms of the product (e.g., diced, chunks, cut, fillet) on the same Form FDA 2541d, provided that:
  - Other factors (e.g., container type or size) do not require separate filing; and;
  - The process information you provide in Section J of Form FDA 2541d applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation of the product form must be filed. The comment section of the filing form should state which formulation product form heats the slowest.
- You may report multiple product packing mediums on the same Form FDA 2541d provided that:

    - Factors other than "product packing medium" (e.g., container type or size) do not require separate filing; and
    - The process information you provide in Section J of Form FDA 2541d applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation of the product packing medium must be filed. The comment section of the filing form should state which formulation packing medium heats the slowest.
- You may report multiple products with minor formulation changes (e.g., a shake base that you produce to have a strawberry-flavored version, and a shake base that you produce to have a vanilla-flavored version) on the same Form FDA 2541d provided that:
    - Other factors (e.g., container type or size) do not require separate filing; and
    - The process information you provide in Section J of Form FDA 2541d applies to each formulation of the product. If the heat transfer rates are different for each product formulation variation, the process for the slowest heating formulation of the product must be filed. The comment section of the filing form should state which formulation heats the slowest.
- Brand names of products generally should not be part of the Product Name. However, you may need to include the brand name as part of the Product Name if it is necessary to distinguish products that are produced using different scheduled processes. You need not submit a separate Form FDA 2541d for each brand name of a product that is manufactured, processed, or packed under more than one brand name if the scheduled process for each brand is exactly the same.

When preparing separate forms that contain much of the same information (such as for a product that you manufacture, process, or pack in multiple container sizes), you may save time by using photocopying. Specifically, you may enter the information that applies to all the products, photocopy the form, and then complete the product-specific information on the photocopies. Each submitted form must be complete. Importantly, each submitted form must have a unique SID (see Step One) and must have an original (not photocopied) signature of an authorized company representative.

We recommend that the authorized representative make and keep a copy of each process filing form.

B. Step 1: Top of Form – Food Canning Establishment Number and Submission Identifier

Provide the FCE number and SID at the top of Form FDA 2541d, before Section A. Leave the "Date Received by FDA" blank (this is for FDA internal use only).

1. Food Canning Establishment (FCE) Number:

We assign a Food Canning Establishment (FCE) number to each physical processing facility that registers using Form FDA 2541 (Ref. 1). Enter the five digit FCE number we provide for the specific establishment (processing location) where the product(s) are

manufactured, processed, or packed after you register that establishment using Form FDA 2541. If you are submitting a process filing at the same time as you are registering your establishment for the first time, you may leave the FCE number blank.

2. Submission Identifier (SID):

Each process filing is identified by a unique Submission Identifier (SID). The SID is a unique number associated with each submitted process filing. You assign the SID. The combination of the FCE number and the SID identifies a specific process filing form.

The SID is a combination of:

- (1) The date (i.e., year, month, and day of the month) that a process filing form is submitted; and
- (2) A sequence number that would distinguish multiple forms submitted on the same date. The sequence number starts with 001 and continues (002, 003) for as long as necessary to uniquely identify all forms submitted on the same date.

If you submit multiple types of process filing forms on the same date (e.g., if you submit three Forms FDA 2541d and three Forms FDA 2541f on the same date), the sequence number would increase by 001 for each submitted form rather than begin again at 001 for each type of form (see examples immediately below).

When you submit paper forms, you assign the SID and include it on the form using the following format:

YYYY-MM-DD/SSS

Where:

YYYY represents the calendar year (e.g., 2013, 2014)

MM represents the month (e.g., 02 for February, 10 for October)

DD represents the day of the month (e.g., 02, 19, 30)

SSS represents the assigned sequence number (e.g., 001, 002, 003).

Examples of SIDs include:

2013-02-22/001: The first Form FDA 2541d submitted on February 22, 2013

2013-02-22/002: The second Form FDA 2541d submitted on February 22, 2013

2013-02-22/003: The third Form FDA 2541d submitted on February 22, 2013

2013-02-22/004: The fourth process filing form, this one a Form FDA 2541f, submitted on February 22, 2013

2013-02-22/005: The fifth process filing form, this one a Form FDA 2541f, submitted on February 22, 2013

2013-02-22/006: The sixth process filing form, this one a Form FDA 2541f, submitted on February 22, 2013

C. Step 2 – Section A. Product Information

1. Food Product Group (Optional):

We request information about "Food Product Groups" to help us understand the nature of your products. The information you provide helps FDA prioritize which commercial processing facilities to inspect. The Food Product Group is optional information (i.e., you are not required to identify the Food Product Group.) If you choose to fill in this information and there is no single best Food Product Group applicable to the product, select "Other."

2. Enter Product Name.

Describe the actual food commodity or formulated food in the container (e.g., beans, green; mushrooms (button); tuna (light); sardines (sild)).

- If the product is named in a foreign language, provide its English equivalent first and then provide the foreign language name in parentheses (e.g., green kidney beans (flageolets) in brine).

  The product name may include scientific names. When a scientific name is in Latin, the product name should also include the common English translation or description of the scientific name (e.g., mushrooms (Agaricus bisporus) pieces and stems, in brine; Beans (Phaseolus vulgaris) in brine)

- Brand names should not be part of the product name unless a brand name is necessary to distinguish products that are produced using different scheduled processes.

Some product names may include qualifying terms that identify unique species, processing methods, or organoleptic or visual properties. Some products may be compartmentalized, and include multiple types of foods. For such products, specify these unique properties. If, however, you are submitting the same Form FDA 2541d for multiple products with minor formulation differences, as described in Section II.A. of these instructions, indicate those minor formulation differences with the product name. For example, if you are submitting the same Form FDA 2541d for beans that you make using green or wax varieties, indicate those varieties as part of the product name. Some examples of product names:

- Enter "Sardines (Sild)," not "Sardines"
- Enter "Radishes, pickled (Szechuan)," not "Radishes"
- Enter "Tuna (light)," not "Tuna"
- Enter "Mixed vegetables, pickled (matsutake meshi-no-moto)," not "Mixed vegetables"

- Enter “Macaroni and cheese entrée with green beans and apple pie,” not “Macaroni and cheese” (This is an example of a compartmentalized shelf stable product).
- Enter “Beans (green or wax),” not “Beans”
- Enter “Mushrooms (button),”not “Mushrooms”

3. What is the form of the product?

The product form relates to the shape or appearance of the product itself (e.g., cut, pieces and stems, whole) rather than the characteristics of the container.

Select one or more product forms listed on the filing form. You may report multiple forms of the product on the same Form FDA 2541d with the caveats discussed in section II.A of this document. If none of options listed on the form apply, select “Other” and enter the product form in the space provided.

4. What is the packing medium?

In general, “packing medium” refers to the liquid portion(s) of a product when the liquid is added over, or added to, the solid portion(s) of a product. You may report multiple product packing mediums on the same Form FDA2541d with the caveats discussed in section II.A of this document.

Select one or more packing mediums listed on the form. If a product is all liquid, select “None (i.e., the product is all liquid).” If there is no packing medium, select “Solid (no packing medium).”

D. Step 3 – Section B. Governing Regulation

Form FDA 2541d only applies to Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, which are regulated pursuant to 21 CFR 108.35 and 21 CFR Part 113. Refer to Ref. 2 of this document. Therefore, Form FDA 2541d identifies these governing regulations and you do not need to add any information to Section B.

E. Step 4 – Section C. Container Type

Each different container type and each different size of the same container type should be filed as a separate Form FDA 2541d. Therefore, for any Form FDA 2541d that you submit, select a single container type. For additional technical information about container types, refer to Appendix – A, Container Types and Shapes.

1. Aluminum/Tinplate/Steel Can

The first container type listed on Form FDA 2541d is for a container of all non-flexible metal (i.e., aluminum,[2] tinplate, or steel can). Do not select Aluminum/Tinplate/Steel Can if the container combines metal in one layer with other materials (e.g., paperboard or a polymer) in other layers.[3]

a) What is the shape of the container?

Select the shape that best applies to the container. If the container is asymmetrical in shape, select "Irregular" and attach a picture or schematic. If none of the shapes apply, select "Other" and attach a picture or schematic.

b) How many pieces are used to construct the container?

A 2-piece container is a container where one end is made as part of the can body. There is no side seam and only one end is attached through the formation of a double seam.

A 3-piece container consists of a can body and two attached ends. A 3-piece container can be identified by the presence of a side seam. The side seam runs the length of the cylinder from one end to the other. Side seams are either cemented or welded. Select the applicable option.

Divider plates are any material used to separate layers of containers. If divider plates are used, select "Yes." Otherwise, select "No." For 3-piece containers, select one option to indicate how the side seam is sealed (i.e., cemented or welded).

c) Is the container a low-profile container?

A low-profile container is a container where the width/diameter of the container is greater than the height (e.g., sardine can).

If yes, answer either question c.i or c.ii. If no, continue to Section D – Container Size.

> Question c.i: If a heat penetration (HP) test was conducted on nested containers, select this option and attach the heat penetration study along with a picture or diagram of the nested containers, then continue to Section D – Container Size.

[2] Note that we consider an aluminum can to be a non-flexible metal container rather than a semi-rigid container.

[3] Note that we consider a combination of metal and other material containers to be a retortable paperboard or semi-rigid container.

Question c.ii: If a heat penetration (HP) test was conducted on non-nested containers, select the option that prevents nesting of containers: brick stacked, lid to lid/bottom to bottom, perforated divider plates, racks, or spiral.

2. Ceramic/Glass

The second container type listed on Form FDA 2541d is for a container of ceramic or glass.

a) What is the shape of the container?

Select the shape that best applies to the container. If the container is asymmetrical in shape (e.g., boot, hat, tree), select "Irregular" and attach a picture or schematic. If the shape options are not applicable, select "Other" and attach a picture or schematic.

b) Do you use perforated divider plates?

Select Yes or No. Divider plates are any material used to separate layers of containers.

c) Is overpressure used during processing of the product to maintain container integrity?

Overpressure is the additional external pressure often used to maintain the hermetic seal during the processing cycle (heating and cooling). This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

If yes, continue to question c.i. If no, continue to c.ii through c.iv.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits prior to the decimal point and one digit after the decimal point and continue to Section D – Container Size.

Question c.ii: What is the percent (%) headspace?

Percent headspace is the fraction of volume of the void (where there is no food product) in the container divided by the volume of the entire container multiplied by 100. Enter the headspace using a maximum of two digits prior to the decimal point and one digit after the decimal point and continue to the next question.

Question c.iii: What is the minimum initial temperature?

Minimum initial temperature (IT) is the average temperature of the contents of the coldest container to be processed at the time the thermal process cycle begins. Enter the minimum initial temperature in degrees Fahrenheit using a maximum of three digits prior

to the decimal point and one digit after the decimal point and continue to the next question.

Question c.iv: What is the vacuum?

Control of the internal pressure depends upon the vacuum in the container. Enter the vacuum in inches of mercury (Hg) using a maximum of two digits prior to the decimal point and one digit after the decimal point.

3. Flexible Pouch

The third container type listed on Form FDA 2541d is for a container of flexible material.

A flexible pouch is a food container that has no fixed shape. Its final shape is defined by the product placed inside it during the filling and sealing process. It is constructed of flexible panels composed of laminated polymers. The composition of laminated polymers varies depending on the food product, the processing method, and the intended use. Some flexible pouches contain a foil layer.

a) What is the shape of the container?

Select the option that applies to the container. For "Irregular" or "Other" option, attach a picture or schematic of the pouch.

b) Is the container physically restricted during processing of the product to control the container thickness?

During processing, the pressure inside the pouch often exceeds the pressure inside the processing vessel. In this instance, the pouch can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the pouch from expanding.

If yes, continue to question b.i to indicate how the container is restricted. If no, continue to question c.

Question b.i: Racks: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Pouches can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, select "Other" and attach a picture of the restraint used.

c) Is overpressure used during the processing of the product to control container thickness?

With flexible pouches, some additional external pressure may be required to conform the container to its maximum dimensions for proper heat penetration and to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

If yes, continue to question c.i. If no, continue to question d.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits prior to the decimal point and one digit after the decimal point.

d) What is the maximum thickness during retort processing?

Pouches can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. Enter the maximum thickness in inches using a maximum of two digits prior to the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and ¼ of an inch, 10.00 is a representation of exactly 10 inches).

e) What is the maximum residual air?

Residual air trapped inside a flexible pouch can cause unexpected expansion during processing. Enter the maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

4. Retortable Paperboard Carton

The fourth container type listed on Form FDA 2541d is for a container of retortable paperboard material.

Paperboard is a thick, paper-based material. While there is no rigid differentiation between paper and paperboard, paperboard is generally thicker than paper (usually more than 0.25 mm thicker (equal to 0.010 inches or 10 points)). A paperboard container is a container where the structure of the container is based on a wood pulp-based core which has the consistency of thick paper or cardboard.

a) What is the shape of the container?

Select the shape that best applies to the container. If the container is rectangular (e.g., juice box, soup box) in shape, select "Rectangular." Otherwise, select "Other" and attach a picture or schematic.

b) Is the container physically restricted during processing of the product to control the container thickness?

During processing, the pressure inside the retortable paperboard carton often exceeds the pressure inside the processing vessel. In this instance, the retortable paperboard carton can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the retortable paperboard carton from expanding.

If yes, continue to question b.i to indicate how the container is restricted. If no, continue to question c.

Question b.i: Racks - For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Retortable paperboard cartons can be restrained by closely placed flat racks or racks that have indentations.

Other – For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, then select "Other" and attach a picture of the restraint that is used.

c) Is overpressure used during the processing of the product to control container thickness?

Overpressure is extra external pressure to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

If yes, continue to question c.i. If no, continue to question d.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits prior to the decimal point and one digit after the decimal point

d) What is the maximum thickness during retort processing?

Retortable paperboard carton can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. Enter the maximum thickness in inches using a maximum of two digits prior to the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and ¼ of an inch, 10.00 is a representation of exactly 10 inches).

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e) What is the maximum residual air?

Residual air trapped inside a retortable paperboard carton can cause unexpected expansion during processing. Enter the maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

5. Semi-Rigid

The fifth container type listed on Form FDA 2541d is for a container of semi-rigid material.

A semi-rigid container is a container where the shape of the container is not altered by filling of product at atmospheric pressures---but can be altered by additional external pressure.

a) What is the shape of the container?

Select the shape that best fits the container. For "Irregular" or "Other" options, attach a picture or schematic.

b) Is this a compartmentalized container?

Compartmentalized containers are containers that hold more than one food product (e.g., corn and green beans where corn and green beans are held in separate sections within a single container) and the food is processed in the single container.

If the container consists of more than one compartment and the compartments contain different food products, select "Yes" and identify the number of compartments. Otherwise, select "No."

c) What is the predominant material used to make the body of the container?

Select the material that, based on weight, is the predominant material used to make the container stock. If you select "Other," enter the information next to "Other."

d) What is the predominant material used to make the lid of the container?

Select the material that, based on weight, is the predominant material used to make the lid stock. If you select "Other," enter the information next to "Other." If the container is a web fed paperboard brick pack, without a lid, select "Not Applicable."

e) How is the lid sealed to the body of the container?

Select the appropriate option. If you select "Other," enter the information next to "Other." If the container is a web fed paperboard brick pack, without a lid, select "Not Applicable."

f) Is the container physically restricted during processing of the product to control container thickness?

During processing, the pressure inside the semi-rigid container often exceeds the pressure inside the processing vessel. In this instance, the semi-rigid container can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the semi-rigid container from expanding.

If yes, continue to question f.i to indicate how the container is restricted. If no, continue to question g.

Question f.i: Racks – For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Semi-rigid containers can be restrained by closely placed flat racks or racks that have indentations.

Other – For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, then select other and attach a picture of the restraint that is used.

g) Is overpressure used during the processing of the product to control container thickness?

Overpressure is additional external pressure required to conform the semi-rigid container to its maximum dimensions for proper heat penetration and to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

If yes, continue to question g.i. If no, continue to question h.

Question g.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits prior to the decimal point and one digit after the decimal point.

h) What is the maximum thickness during retort processing?

Semi-rigid containers can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. Enter the maximum thickness in inches using a maximum of two digits prior to the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and ¼ of an inch, 10.00 is a representation of exactly 10 inches).

i) What is the maximum residual air?

Residual air trapped inside a semi-rigid container can cause unexpected expansion during processing. Enter maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

6. Other Container

The sixth container type listed on Form FDA 2541d is for a container of a type other than the ones listed above.

Select "Other" when none of the container types listed on the form applies.

a) Attach a schematic or picture of the container.

b) Specify the material that, based on weight, is the predominant material used to make the container stock. This is the material that constitutes the highest weight value of the container stock.

c) Specify the material that, based on weight, is the predominant material used to make the lid stock. This is the material that constitutes the highest weight value of the lid stock. If the container does not have a lid, specify Not Applicable.

d) Specify the method used to seal the lid to the body. If the container does not have a lid, specify Not Applicable.

F. Step 5 – Section D. Container Size

Section D includes one required field (D.1 – Dimensions) and one optional field (D.2 – Net Weight). Products come in a variety of container shapes (see section II.C of this document). For cylindrical (including bowl and oval) shapes, use Option "a" to report the container size. For rectangular (including trays) shapes, irregular shapes, or pouches, use Option "b" to report the container size. Report container dimensions in English units (number of whole inches and sixteenths of an inch).

Refer to Appendix – B, Container Dimension Measurements for examples.

1. Dimensions:

a) Diameter and Height. Use this option only for cylindrical (including bow and oval) shaped containers.

b) Length, Width and Height. Use this option for container shapes other than cylindrical.

When entering dimensions for diameter, length, width, and height, express the dimensions by creating a round number that is a code reflecting the dimensions in inches. The first part of the code represents the whole number of inches and the last two digits represent the fraction of an inch in sixteenths. For example:

- If the dimension is 12 and 8/16 inches, create the code from 12 and 08 – i.e., 1208.
- If the dimension is 5 and 15/16 inches, create the code from 5 and 15 - i.e., 515.
- If the dimension is 3 and ¾ inches, first express the ¾ inches in sixteenths - i.e., 12/16. Then create the code from 3 and 12 - i.e., 312.
- If the dimension is 4 inches, create the code from 4 and 00 - i.e., 400.
- If the dimension is 4 and 1/8 inches, first express the 1/8 inches in sixteenths - i.e., 2/16. Then create the code from 4 and 2 - i.e., 402.

Rounding may be necessary for sizes that are less than one sixteenth of an inch. Rounding can be up or down depending on the measurement. If the measurement is closer to the "higher" sixteenth, round up; if the measurement is closer to the "lower" sixteenth, round down. For example:

- If the diameter is 3 and 7/16 inches and the width is 2 inches and 1/4 of one 16th inches, the rounded dimensions will be 307 x 200
- If the diameter is 4 5/16 inches, the width 3 and 1/16 inches, and height is 0.906 (14/16ths and 1/2 of one 16th of an inch), the rounded dimensions will be 405 x 301 x 015

2. Net Weight (Optional):

This question provides the opportunity for you to include the net weight of your product. Although you are not required to enter this information on this filing form, entering the information can assist FDA inspectors examining product in matching a product under examination to the product described in this filing form.

Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food.

Enter the net weight in ounces if you choose to provide this optional information using a maximum of three digits prior to the decimal point and two digits after the decimal point.

G. Step 6 – Section E. Processing Method: Thermally Processed Non-Aseptic System

Processing method is a general description of how the product in the container is treated during the heating process (e.g., still, agitating).

1. What is the finished equilibrium pH of the product after processing?

Enter the representative pH of the product after processing using a maximum of two digits prior to the decimal point and two digits after the decimal point. In instances where there is no decimal value, the decimal portion will be two zeros.

2. Heating medium

Heating medium is the method used to convey heat to a product during a thermal process (e.g., water immersion, steam, water cascade, water spray, steam-air, high pressure assisted). Select the one heating medium that comes in contact with the container.

a) Steam Air with a fan - A Steam-air medium is a carefully proportioned mixture of steam and air. It does not use water during the heating process.

If you select "steam-air with a fan" as the heating medium, you must attach a heat distribution study.

The other available heating mediums are: High pressure assisted, Microwave, Ohmic, Steam, Water immersion, Water cascade, Water spray, or Other. If you select "Other," enter a description of the heating medium next to "Other."

H. Step 7 – Section F. Process Mode

1. Mode

There are two overall process modes: agitating (where there is container movement and orientation) and still (where there is no container movement).

Select one process mode and select from the available options applicable to that mode. Then continue to question F.2.

a) Agitating

i. Axial (can apply to either batch or continuous)

In an axial rotating system, containers travel on their side and rotate on a longitudinal axis around the inner circumference of the processing vessel shell in a continuous or batch process. Select either "Batch" or "Continuous."

ii. End over end (only applies to batch).

In an end-over-end system, the containers are loaded vertically into a crate and the crate spins vertically 360 degrees from top to bottom.

iii. Oscillation (only applies to batch). Select one: high frequency or low frequency

In an Oscillation system, containers vibrate laterally at either a low or high frequency.

b) Still

i. Horizontal

In a horizontal still retort, the processing shell is horizontal and containers may be loaded horizontally, vertically, or randomly (jumble) from one end of the retort. If the retort has two doors, the product enters through one door and exits through the other door for processing "traffic" control.

ii. Vertical

In a vertical still retort, the processing shell is oriented vertically and containers are loaded from the top. Containers may be positioned, horizontally, vertically, or randomly (jumble). Some of these systems are crateless systems where containers are randomly loaded through the top and removed through the bottom.

2. Cooker: What type of cooker do you use?

Select one cooker type. If you select "Other," enter the cooker type next to "Other" and attach supporting documentation.

I. Step 8 – Section G. Process System Critical Factors

Section G of the form requests information about critical factors associated with the process system. (Note that this is distinct from Section H of the form, which requests information about critical factors for the product.) Under 21 CFR 113.3(f), critical factor means "any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility."

1. What is the filling method(s) used to fill the product into the container?

We list several available filling methods. Select as many as apply. Below, we describe the listed filling methods:

- Hand filling - the primary ingredient(s) are placed in the food container manually. Select this method even if the brine/sauce/oil is topped off mechanically, after the primary ingredient is placed in the container by hand.

- Piston filling - liquid/paste/semi-solid is measured and filled by the positive displacement of a piston evacuating a fixed volume cylinder.

- Pocket filler - for solids/particulates that are gravity fed into a fixed volume pocket, which is then used to put the measured ingredient into the food container.

- Vibrating/Tumble filling - the solids are mechanically dropped into the can with or without the assistance of vibration.

- Volumetric filling – the liquid/sauce food product is mechanically filled.

2. How many phases are used to fill the container with the product?

A phase is a stage of filling the product into the container. Many formulated products contain several stages of filling where each ingredient (e.g., soup that contains vegetable, broth, meat) is filled separately to assure a fixed ratio between them and minimum/maximum quantities of each ingredient. Select the number of phases appropriate to your filling method.

3. Is the product vacuum packed?

Vacuum packed products are solid/dry packed without any fluid, and the majority of the air is removed from the container by mechanical vacuum. If the product is vacuum packed, select "Yes." Otherwise, select "No."

4. What is the container position in the retort?

By "container position in the retort," we mean how the containers are arranged in the retort (e.g., horizontal, random). If you selected "Agitating" in Section F – Process Mode of the form, skip this question. Otherwise, select one of the available container positions. Below, we describe the listed container positions.

- Brick stacked - the containers on each layer are overlapping/offset from the containers on the layers below/above.
- Horizontal - the containers are on their sides.
- Jumbled/Random - there are no layers and there is no order to the crate/retort loading. Containers with a jumble load are at a variety of angles and positions with relation to other containers.
- Lid down - the containers are loaded with a specific orientation of the container lid facing the bottom of the retort.
- Lid up - the containers are loaded with a specific orientation of the container lid facing the top of the retort.
- Vertical - the containers are upright and layered, but there is no specific coordination between the layers (unlike brick staking).

5. Minimum Come-Up-Time

If the heating medium you selected in Section E – Processing Method Thermally Processed Non-Aseptic Systems was "High pressure assisted," "Microwave," "Ohmic," or "Steam," of the form, skip questions G.5 and G.6.

Minimum come-up-time is the amount of time between the time the steam is turned on and the time the retort achieves processing temperature at all locations within the retort. Enter the minimum amount of time in minutes using a maximum of two digits prior to the

decimal point and one digit after the decimal point and attach a temperature distribution study.

6. Minimum Water Flow Rate

If the heating medium you selected in Section E – Processing Method Thermally Processed Non-Aseptic Systems was "Steam air," of the form skip this question.

The minimum water flow rate refers to the minimum volume of water per unit time, flowing through a retort system that requires water circulation (i.e., water spray, water cascade, water immersion) in the retort. Enter the flow rate in gallons per minute (gpm) using a maximum of three digits prior to the decimal point and one digit after the decimal point.

J. Step 9 – Section H. Product Critical Factors

Section H of the form requests information about critical factors for the product. (This is in contrast to Section G of the form, which seeks information about critical factors associated with the process system.) As discussed above, critical factor means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

1. Does the product contain particulates?

Particulates are any solid or semi-solid pieces that may erode or diminish during processing, but are still discernable in the finished product. If you select "Yes," continue to question H.1.a. Otherwise, select "No" and continue to question H.2.

a) Is controlling particulate size a critical factor?

Some particulates are naturally limited in size (e.g., rice, beans, peas, corn kernels) or mechanically modified in size (e.g., cut, diced). If failing to control the size could impact heat penetration into the particulate or impact convective heating, select "Yes" and continue to questions H.1.b-H.1.d. Otherwise, select "No" and continue to question H.2.

b) What is the maximum dimension of the particulate size?

Enter the maximum dimension of the particulate size in inches or millimeters using a maximum of two digits prior to the decimal point and three digits after the decimal point.

c) Does your product contain fines?

Some of the processes used to standardize particle size result in the creation of small pieces, called fines. If the distribution of the fine pieces throughout the production is not controlled, they can aggregate in a small group of containers or a single container, impacting heat penetration. If your product contains fines, select "Yes" and continue to question H.1.c.i. Otherwise, select "No" and continue to question H.1.d.

Question c.i: What is the maximum percent?

Enter the maximum percent of the fines using a maximum of three digits prior to the decimal point and one digit after the decimal point.

d) Is full rehydration of the particulate a critical factor?

If full hydration is necessary before filling, select "Yes." Otherwise, select "No."

2. Does the product contain any dry ingredients?

Some processors hydrate dry ingredients before filling the containers and other processors control the liquid-dry ingredient ratio when filling, allowing for hydration in the containers during the thermal process. If your product contains dry ingredients, select "Yes" and continue to question H.2.a. If dry ingredients are hydrated before filling the container, select "No" and continue to question H.3.

a) What is the minimum % moisture of dry ingredients before processing?

Enter the percent moisture using a maximum of two digits prior to the decimal point and two digits after the decimal point. If the minimum % moisture is not a critical factor, select "Not Applicable."

3. How are pieces arranged in the container?

In some processes, arrangement of the solid pieces in the container can impact heat penetration (e.g. with asparagus products, the direction of the asparagus spears can affect heat penetration).

Select one of the available options for how pieces are arranged. If you select "Other," identify how the pieces are arranged next to "Other" and attach an explanation. If the arrangement of pieces in the container is not a critical factor, select "Not Applicable."

4. Does the % solids affect the heating of the product during processing?

In some processes, the amount of solids in the container can impact heat penetration. If the percent solids affects the heating, select "Yes" and continue to question H.4.a. Otherwise, select "No" and continue to question H.5.

a) What is the % solids?

Enter to the nearest tenth the maximum percent solids in the product that is critical to the process using a maximum of two digits prior to the decimal point and two digits after the decimal point.

5. Is the finished equilibrium pH of the product after processing (identified in Section E) critical to the process?

In some instances, the thermal process delivered to a low-acid food product is calculated based upon the pH of the finished product. If pH is critical to the thermal process of the product, select "Yes." Otherwise, select "No."

6. Does consistency/viscosity affect the heating of the product?

Product heating is typically based upon convection and/or conduction. For products heated by convection and/or conduction, the consistency / viscosity of the liquids in the container can impact heat penetration during thermal processing. If the heating of the product is based upon control of the consistency/viscosity, select "Yes" and continue to questions H.6.a-H.6.c. Otherwise, select "No" and continue to question H.7.

a) What instrument is used to measure the consistency/viscosity?

Enter the instrument used (e.g., Brookfield, Brabender)

b) What is the temperature when you measure the consistency/viscosity?

Enter the product temperature in degrees Fahrenheit that the reading is to be taken at using a maximum of three digits prior to the decimal point and one digit after the decimal point.

c) What is the consistency/viscosity? What is the unit of measure?

Enter the measured value using a maximum of three digits prior to the decimal point and two digits after the decimal point. Specify the unit of measure either by selecting "Centipoise," or by selecting "Other." If you select "Other," enter the units of measure next to "Other."

Examples of other units of measure:

- Pascal-second (Pa.s)
- Saybolt Seconds Universal (SSU)
- Stokes (St)

7. Is starch added to maintain consistency/viscosity of the product?

If starch is added to achieve a desired consistency/viscosity, select "Yes" and continue to questions H.7.a-H.7.b. Otherwise, select "No" and continue to question H.8.

a) What is the maximum % starch added?

Enter the maximum percent starch of the total product formula weight using a maximum of two digits prior to the decimal point and two digits after the decimal point.

b) What type of starch is added?

Enter the type of starch added to the product.

Examples of starch types:

- Corn starch
- Potato starch

8. Are other binders added?

If binders other than starch are added to achieve a desired consistency/viscosity, select "Yes" and continue to questions H.8.a-H.8.b. Otherwise, continue to question H.9.

a) What is the maximum % binder added?

Enter maximum percent binder of the total product formula weight using a maximum of two digits prior to the decimal point and two digits after the decimal point.

b) What type of binder is added?

Enter the type of binder added to the product.

Examples of binder types:

- Gelatin
- Keltrol (seaweed extract)

9. Does syrup strength affect the heat penetration during processing of the product?

Syrups are included as ingredients in many products to achieve a desired taste and sensory quality. If adding syrups is critical to how the product heats, select "Yes" and continue to question H.9.a. Otherwise, continue to Section I – Scheduled Process Source.

a) What is the brix measurement?

Degree Brix is the % sugar, by weight, of an aqueous solution. Enter the maximum degrees (Brix) to the nearest two decimal place of a degree (e.g., 30.03) using a maximum of two digits prior to the decimal point and two digits after the decimal point.

K. Step 10 – Section I. Scheduled Process Source

1. Process Source:

a) What is the Process Source?

The process source establishes the scheduled process. Scheduled processes for low-acid foods must be established by qualified persons having expert knowledge of thermal

processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations.

Enter the name of the process source (e.g., company, individual, or outside entity such as a university) who scientifically established the scheduled process(es) and attach the support documentation containing the process recommendations (e.g., letter, bulletin, scientific paper). You may refer to 21 CFR 113.83 for more detailed requirements concerning establishing scheduled processes. Below, we provide some examples of how to name the process source.

- If the process was established by your facility, enter the facility's name.
- If the process was established by a university or other outside entity, enter the name of the university or other outside entity (followed by the name of an individual, as appropriate).
- If the process was established by a reference source document or publication, enter the reference source document.

b) What is the date of the Process Source?

Enter the date of the process source document that is attached in month/day/year format.

2. What is the Manufacturer's Name and the Sterilizer Model?

If you selected the process mode "Still" under Section F – Process Mode of the form and you selected the heating medium "Steam" in Section E – Processing Method – Thermally Processed Non-Aseptic System of the form, you may, if applicable, select "Unknown/Locally Made" and attach pictures and supporting documentation.

Otherwise, enter the manufacturer's name and the model of the sterilizer. Do not include in the name "still," "agitating," "hydrostatic," "vertical," or "horizontal."

L. Step 11 – Section J. Scheduled Process

Under 21 CFR 113.3(r), scheduled process means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. The scheduled process, which is the process established by a qualified process source as described in section II.K.1 of this document, may be in excess of what is necessary to ensure destruction of microorganisms of public health significance.

List each process on a single line, except for a multiple-step process. In a multiple-step process, only list the minimum initial temperature for the first step. In addition, only list the cumulative lethality value (i.e. total F value for all steps) for the last step.

For each listed process, you must provide information in columns 1-6. Whether you must provide information in columns 7 through 13 depends on the processing system. In the

instructions for columns 7 through 13, we identify the processing systems that require data entry in those columns.

1. Column 1. Process No.

Each process has its own process number. Enter the number 1 in the first row, the number 2 in the second row, and continue entering numbers in increments of 1 for each scheduled process that you list. The process number increases by increments of 1 regardless of the number of steps in each scheduled process.

2. Column 2. Step

A process may have one or more steps. For a single-step process, enter the number 1 in column 2. When the process has multiple steps, enter the number 1 for the first step, the number 2 for the second step, and continue entering numbers in increments of 1 for each subsequent step.

3. Column 3. Minimum Initial Temperature

Minimum Initial temperature (IT) is the lowest initial temperature permitted in the scheduled process. IT is the average temperature of the contents of the coldest container to be processed at the time the thermal process cycle begins. This may be calculated by agitating/shaking the filled, sealed container to mix the contents before obtaining this value.

Enter the minimum initial temperature in degrees Fahrenheit using a maximum of three digits prior to the decimal point and one digit after the decimal point.

4. Column 4. Process Time

Enter the duration of the process time using a maximum of three digits prior to the decimal point and two digits after the decimal point. If the duration is a whole minute, enter the number of minutes and two zeros for the decimal portion.

Examples of how to enter process time:

- If the process time is 15 minutes and 30 seconds, enter 15.50
- If the process time is 150 minutes and 0 seconds, enter 150.00

5. Column 5. Process Temperature

Enter the temperature of the step in degrees Fahrenheit using a maximum of three digits prior to the decimal point and one digit after the decimal point.

6. Column 6. Fo (F18/250)

Enter the number of minutes that the process requires to achieve commercial sterility using a z value of 18 degrees and a reference temperature of 250 degrees Fahrenheit. Enter the number of minutes using a maximum of two digits prior to the decimal point and two digits after the decimal point.

Examples of how to enter the Fo:

- 6.00
- 6.35

7. Column 7. Thruput (Containers per Minute)

Answer this question only if you selected "Agitating – Axial Continuous" in Section F of the form. Enter the number of food containers going through the processing system per minute using a whole number with a maximum of four digits and no decimal point. The value entered should be the maximum number of containers per minute that provides the basis for the filed process time.

8. Column 8. Headspace

Answer this question only if you selected "Agitating" in Section F of the form. Select one of the following options: 1) Net, 2) Gross, 3) NA.

Net headspace is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the lowest inside surface of the lid. Gross headspace is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

If you select net or gross headspace, enter in this column the value in inches using one digit prior to the decimal point and four digits after the decimal point. If you enter a zero as the digit prior to the decimal point, you must follow the zero with a decimal value (e.g., 0.125). If you select "NA," do not enter any numerical values in this column.

9. Column 9a. Reel Speed

Answer this question only if you selected "Agitating - End Over End" or "Agitating - Axial" in Section F of the form. Enter the reel speed in rotations per minute (rpm) of the agitation that provides the basis for the filed process time and report the value using a maximum of two digits prior to the decimal point and two digits after the decimal point.

10. Column 9b. Reel Diameter

Answer this question only if you selected "Sterlimatic" in Section F of the form. Enter the diameter of the reel in inches using a whole number with a maximum of three digits and no decimal point.

11. Column 9c. Steps per Turn of the Reel

Answer this question only if you selected "Agitating - Axial Continuous" in Section F of the form. Enter the number of containers held in a 360 degree rotation of the reel that provides the basis for the filed process time, using a whole number with a maximum of two digits and no decimal point.

12. Column 9d. Chain / Conveyor Speed

Answer this question only if you selected "Hydrolock" or "Hydrostat" cooker type in Section F of the form. Select one of the available options of: 1) Feet; 2) Carriers; 3) Flights. In this column, enter the value for the speed per minute using a maximum of three digits prior to the decimal point and three digits after the decimal point.

13. Column 9e. Cooker Capacity

Answer this question only if you selected "Sterilmatic" in Section F of the form.

Enter the maximum number of containers that the cooker shell holds that provides the basis for the filed process time, using a whole number with a maximum of four digits and no decimal point. Do not include infeed or discharge valves.

14. Column 9f. Frequency Strokes per Minute (Oscillation Agitating ONLY)

Answer this question only if you selected "Agitating - Oscillation" in Section F of the form. Enter the strokes per minute using a maximum of three digits prior to the decimal point and two digits after the decimal point.

15. Column 10. Maximum Fill Weight

The maximum fill weight does not include packing liquid that is not customarily consumed with the food. The maximum fill weight is recorded before processing and does not include the weight of the container or covering liquid.

Enter the maximum fill weight in ounces using a maximum of three digits prior to the decimal point and two digits after the decimal point. If the process authority determines this is not critical to the process, select "NA" under the column header and do not enter any numerical values.

16. Column 11. Minimum Free Liquid at Closing

Answer this question only if you selected "Yes" to question G.3. (product vacuum packed) under Section G of the form. Enter the amount of free liquid (e.g., water and/or brine) using a maximum of two digits prior to the decimal point and two digits after the decimal point.

17. Column 12. Minimum Container Closing Machine Gauge Vacuum

Answer this question only if you selected "Yes" to question G.3. (product vacuum packed) under Section G of the form . Enter minimum container closing machine gauge vacuum in inches of mercury (Hg) using a maximum of two digits prior to the decimal point and two digits after the decimal point. Also enter the temperature in degrees Fahrenheit plus or minus 3 degrees as specified by the process source using a maximum of three digits prior to the decimal point and two digits after the decimal point.

18. Column 13. Other

If there are any other critical factors whose values have been specified by the process source as critical to the delivery of the scheduled process, enter them in the column heading and provide the applicable values for each scheduled process. If no additional critical factors have been identified by the process source, leave this column blank.

Example for Other:

- Cooling Water Temperature – 100 degrees F

19. Comments:

Enter any additional information you feel is pertinent to the product and/or the scheduled process critical factor(s). Comments are optional unless you report multiple forms of the product, multiple packing mediums, or multiple product variations, in which case comments may be required in some circumstances as discussed in section II.A – General Information in this document.

20. Full Name, Signature, and Date

Print the first and last name of the person authorized to represent the facility, as well as the FCE facility name, state (for US) or province (for foreign countries), and country. The person authorized to represent the facility must sign and date the form and provide the authorized person's telephone number.

III. How to Contact FDA or Obtain Help

You may contact us:

- By Email at LACF@fda.hhs.gov;
- By telephone at 240-402-2411; and

- By mail at the address immediately below.

Food and Drug Administration
LACF Registration Coordinator (HFS-303)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

IV. References

1. Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format

2. LACF/AF Precursor Questions

V. Appendix

A. Container Types and Shapes

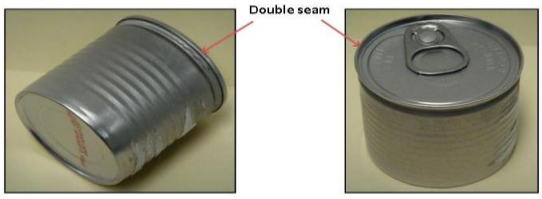

Figure 1 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams

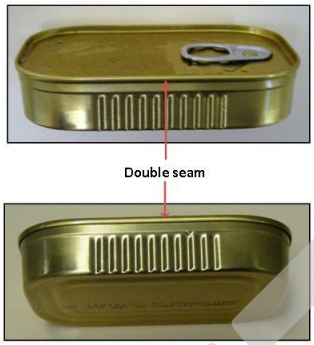

Figure 2 – Low-Profile Rectangular Shape 2-Piece Aluminum Containers

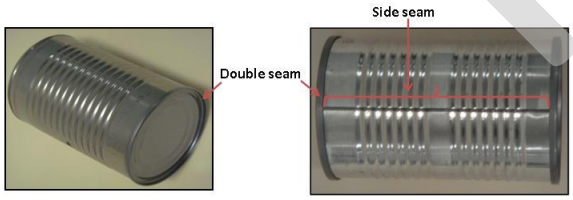

Figure 3 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam

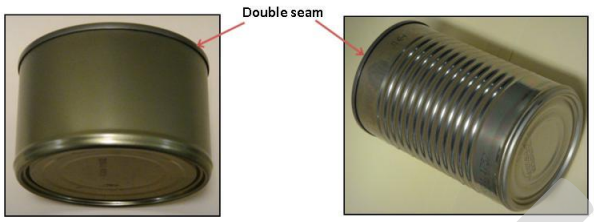

Figure 4 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam

Figure 5 – Flexible Pouch

Figure 6 – Glass Containers

Figure 7 – Semi Rigid Body, Oval Shape Containers with Heat Seal

Figure 8 – Semi Rigid Body, Rectangle Shape Containers

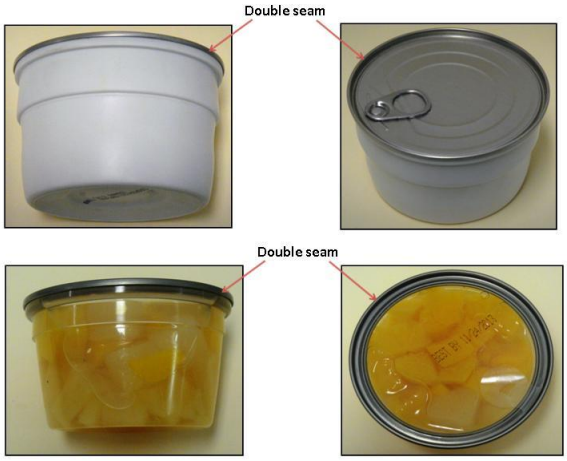

Figure 9 – Semi Rigid Body with an Aluminum Double Seam

Figure 10 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal

Figure 11 – Semi Rigid Body with Heat Seal

B. Container Dimension Measurements

Container dimension measurements should always be measured from the outside edge of the container. Below, we list different types of materials and descriptions of how to properly measure the dimensions of the container.

1. Cylindrical Measurement

Measure the diameter from the outside of the double seam on the container. Measure the height from the top of the double seam to the opposing double seam top. If the can is a two piece can, measure from the top of the double seam to the furthest point on the other end. For glass bottles or unusually shaped cylindrical containers, always measure the widest part of the container.

For heat-sealed, semi-rigid containers, do not measure the sealing flange as part of the container dimensions. Only measure from the inner edge of the flange where the seal edge meets the chamber holding the food.

When measuring cylindrical shaped containers, list diameter x height (e.g., 0211 x 0400 for a 2 11/16 inch x 4 inch container).

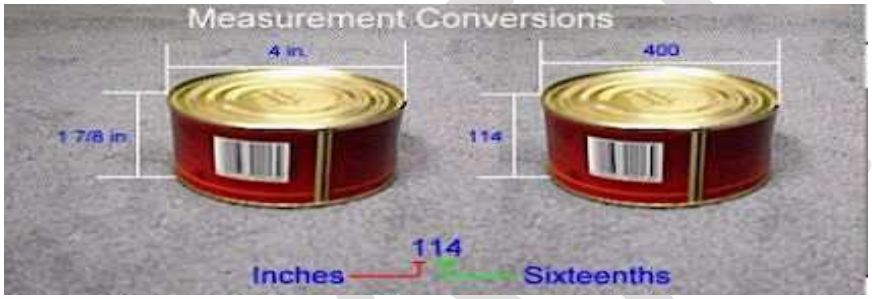

Figure 12 – Measurement of a Cylindrical Shape Container.

When measuring unusually shaped cylindrical containers, always measure the widest part of the container.

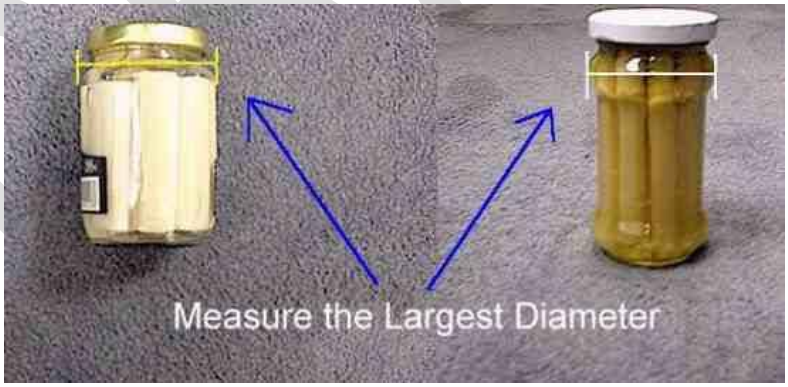

Figure 13 – Measurement of an Unusual Shape Cylindrical Container.

2. Oval Shape Measurement

When measuring unusually shaped oval containers, always measure the widest part of the container.

Figure 14 – Measurement of an Oval Shape Container

Figure 15 – Measurement of Outer Edges of Container

3. Rectangular Shape, Rectangular Tray and Low-Profile Measurement

For all rectangular containers (including trays), list length (longest dimension) x width (second longest dimension) x height; for example, list 0405 x 0301 x 0014 for a container that is 4 5/16 inches long, 3 1/16 inches wide, and 14/16 of an inch.

For a rectangular can, measure the length and width from outside of the double seam. When measuring the height of the container, measure from the top of the double seam to the furthest point on the bottom.

For a rectangular pouch, measure from the inner edge of the seams for the length and width. For the height, measure the thickness at the thickest point.

For paper board rectangular containers, measure the length, width, and height from the outside edge of the container.

4. Rectangular Shape Measurement

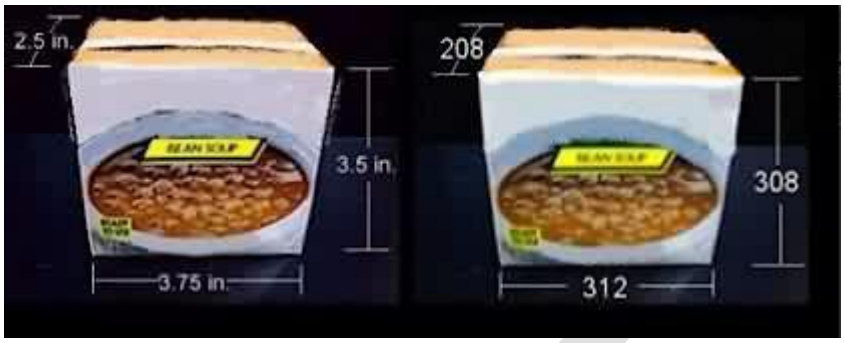

Figure 16 – Measurement of a Rectangular Shape Container

5. Rectangular Tray Measurement

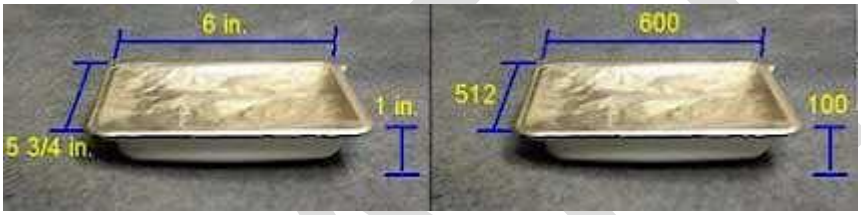

Figure 17 – Measurement of a Rectangular Tray Shape Container

6. Low-Profile Measurement

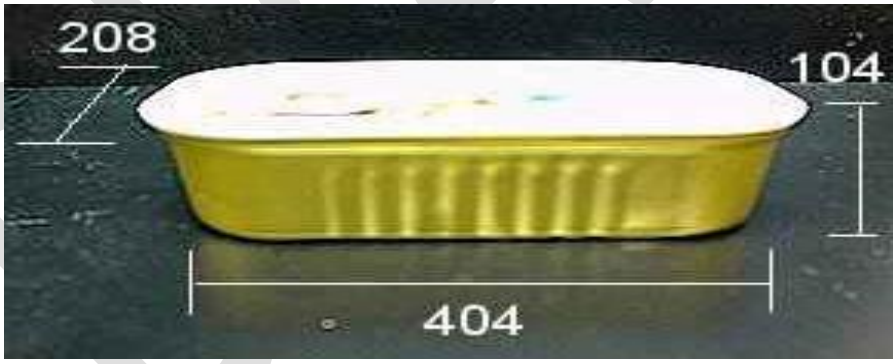

Figure 18 – Measurement of a Low-Profile Container